RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy Research

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Comment

DON HRPP: "Getting in Front of the Aircraft"

On April 29, 2005, Under Secretary of the Navy Dionel Aviles signed an Executive Decision Memorandum that stood up the Navy's Human Research Protection Program, or DON HRPP.

The Under's EDM designated the Surgeon General as the sole point of responsibility for approving and renewing Assurances for Navy commands that conduct research with human subjects.

The EDM also authorized the SG to delegate to the Chief of Naval Research authority for monitoring and oversight of all human research protection activities carried out by the Systems Commands, the fleet and training commands, and all "extramural" activities, such as universities, that conduct Navy research with human subjects.

The signing of the EDM averted the shutdown of all Navy human subjects research programs.

The Office of the Director, Defense Research & Engineering (DDR&E), issued the shutdown threat in late 2004, following a review that found that all of the military services, along with the DoD agencies, needed to update their polices on human research protections.

In January of last year, Surgeon General Vice Adm. Don Arthur and then-CNR Rear Adm. Jay Cohen stood up a HRPP Working Group led jointly by Dr. Tim Singer of ONR and CAPT Eileen Villasante, who then ran the BUMED Human Research Protection Program.

The Working Group rewrote the Navy's human research protections instruction, drafted a funding plan, and produced a library of other documentation, while coordinating the program standup with DDR&E, the CNR, and the SG.

Today, Villasante wears two hats, as head of the Department of the Navy's HRPP and as the Surgeon General's Special Assistant for Research Protections. Singer now is the Acting Head of ONR's new Research Protections Division.

The HRPP team has completed staffing of the new instruction (SECNAVINST 3900.39D), now awaiting signature.

The team now is developing an education plan, training program, HRPP website, and staffing plans. In November the original Working Group made its first site visit, to the Navy Experimental Diving Unit in Panama City, Fla., and is looking at a schedule of visits to medical and fleet commands for 2006.

In December, DON HRPP staff members attended the PRIM&R-ARENA conference in Boston and briefed a presentation called "Getting in Front of the Aircraft." The pitch mapped out the mission of the new DON HRPP to develop the policy and procedural tools to safeguard the welfare of human subjects who participate in Navy research.

The DON HRPP team is laying the groundwork for a program that carries out that mission. The team is standing by to help the Navy's medical, fleet, and training commands, the SYSCOMs, as well as the extramural researchers, do what is necessary to ensure they're protecting their human subjects.

By getting human protections right, Navy researchers can push harder on meeting the USN's larger research mission: developing and fielding to Navy and Marine Corps units the innovative systems and technologies that warfighters need.

Also in this Issue of RPU

Director's Page

Focus: Communications, Assurances, Research Review

By CAPT Eileen Villasante

In just a few words, I want to pass along new guidance on communicating with the Department of Health and Human Services' Office of Human Research Protections, or OHRP, and reinforce understanding of two critical elements of Navy human research protection: assurances and research review.

Communications Outside DoD

The Director, Defense Research and Engineering (DDR&E) requests that all communications with the OHRP be routed through DDR&E, such that effective immediately, commands may not correspond directly with OHRP. Instead they should forward all communications with OHRP to the DON HRPP.

Institutional Assurances

Each Navy and Marine Corps command that seeks to conduct research with human subjects must obtain its own Department of Defense-Navy Assurance approved by the Surgeon General *prior to reviewing or conducting research*. The Assurance documents the command's promise to adhere to the ethical principles and regulatory requirements for the protection of human subjects in research.

Assurances are assigned by the SG to commands—not to investigators or to specific research protocols.

Commanders, Commanding Officers, Officers-in-Charge, or Heads of the Activity serve as Institutional Signatory Officials, or ISOs, for Assurances.

An Assurance identifies specifically the command or institution it covers. Assurances are not "portable" and cannot be transferred to other commands. The Human Research Protection Program maintains a list of approved DoD-Navy Assurances.

Review of Research

In addition to the requirement for a DoD-Navy Assurance for the institution, all human subject research must be reviewed for scientific merit. The scientific review is followed by an institutional review board (IRB) review. The IRB that conducts the review must be identified in the Assurance. The IRB review cannot be transferred when investigators deploy, change duty stations, retire, or move to the reserves.

CAPT Eileen Villasante, Ph.D., MSC, is Director, DON HRPP and Special Assistant to the Surgeon General for Research Protections

Write to us! The DON HRPP now has a direct email address: humanresearch@us.med.navy.mil

Streamlined Assurance Application Directions Coming

The DON HRPP has released new directions for completing Assurance applications and Joint Research Review Agreements.

The new directions, the DON HRPP hopes, will clarify the application process and give the HRPP team a clearer picture of the human research programs that apply for or renew Assurances. Commands and institutions submitting applications also must complete a self-assessment checklist.

The updated Assurance application directions clarify procedures for institutions based on approaches to providing for Institutional Review Board review, including those that use an affiliated IRB or the IRB of another institution. The new directions stress, though, that an Assurance doesn't substitute for institutional policies for providing management and oversight of research with human subjects.

Also now available is an Addendum to the Federalwide Assurance of Protection for Human Subjects, for use by institutions with FWAs that conduct research or collaborate with others on Navy-supported human subject research.

RPU Interview

Villasante: "Reaffirming the Commitment to Protecting Human Subjects"

CAPT Eileen Villasante, a native of Long Island, N.Y., was named Special Assistant to the Surgeon General for Research Protections in fall 2005. She was commissioned in 1984 after earning her Ph.D. in parasitology at the University of Notre Dame. She then led parasitology research at Navy labs in Indonesia and Peru. In the mid-1990s she served as scientific director at the USN's research unit in Cairo, the Navy's largest overseas laboratory. She conducted malaria research at the Naval Medical Research Center, and served as NMRC's director of field laboratories. She became director of the Human Research Protection Program in November 2004, following a tour at the Army's Medical Research and Materiel Command. Last year she co-chaired, with Dr. Tim Singer of the Office of Naval Research, the DON HRPP Working Group.

Tell us about the evolution of the Navy's human subjects research program.

VILLASANTE: The Navy, of course, long has had a key role in protecting human subjects in research. The current effort is based on the Navy's response last year to the recognition that the program, like those of the other services, needed to do a better job of implementing the federal and DoD regulations governing human research protections. The Surgeon General and Chief of Naval Research organized the HRPP Working Group that mapped out the current DON HRPP. In April of last year the Under Secretary of the Navy signed an Executive Decision Memorandum standing up the program.

What were some of the highlights?

VILLASANTE: Without doubt the biggest was the complete revision of the current Navy instruction, which now is awaiting signature. We also coordinated extensively with the SG and CNR on numerous policy and position papers aimed at fleshing out the program.

Discuss the different roles of the Surgeon General and Chief of Naval Research.

VILLASANTE: The Under's memorandum assigned the SG as the single point of accountability for the Navy's human research protection program and the authority for approving Assurances to conduct human subject research. The SG has delegated to the CNR the responsibility for monitoring compliance by the Navy's Systems Commands, training commands and operational forces, and the universities and private companies that conduct research.

The Naval Research Laboratory has tested a vest that shields personnel from the effects of improvised explosive devices. **USN Photo**

What are the key challenges you're facing?

VILLASANTE: The main challenge is reaffirming the Navy's commitment to safeguarding the health and welfare of all persons who participate in Navy-sponsored research.

We're also working to educate the many organizations that conduct human subject research on the requirements they must meet, in terms of getting their policies in shape and applying for an Assurance to conduct Navy-sponsored research.

What are some key events in the next few months?

VILLASANTE: Right now we're working to stand up a staff to carry out our education and monitoring efforts, and setting up a website, which will be an important information resource. We're also looking at a schedule of site visits to medical commands and activities, and fleet and training units.

Kickoff Site Visit

NEDU: Diving to Support the Fleet

In November 2005 the DON HRPP Working Group traveled to the Navy Experimental Diving Unit, or NEDU, in Panama City, Fla. The visit aimed at providing close-up perspective on NEDU's human research protection initiative as part of an overall assessment of the program, which has applied for renewal of its Assurance.

NEDU celebrated its 75th anniversary four years ago. The command carries out demanding testing of diving procedures and equipment that could be adopted by the Navy divers serving with operational fleet units.

The NEDU team also conducts research in bioengineering and biomedical and environmental physiology to support Navy undersea operations. NEDU provides cutting-edge technical and operational recommendations to the Naval Sea Systems Command in support of the fleet.

NEDU's diving team of approximately 120 personnel includes the Navy's most experienced and best-trained divers who have logged more than 1,000 man-years of diving for such missions as salvage, sea-air-land operations, and explosive-ordnance disposal.

The Naval Sea Systems Command and Marine Corps Systems Command generate most of NEDU's research protocols, but NEDU also develops some of its own protocols.

NEDU's campus encompasses an Ocean Simulation Facility, Experimental Test Pool, Environmental Chamber, Experimental Diving Facility, as well as labs and data-analysis facilities.

The OSF can simulate sea-pressure conditions to a maximum depth of 2,250 feet seawater (fsw). The OSF consists of a 55,000-gallon wet chamber and five linked dry working chambers.

The chamber temperatures can be set from 28 to 104 degrees Fahrenheit. Divers use the dry chambers as living space during extended dives. The dry chambers also can be used for altitude-simulation studies, to altitudes up to 150,000 feet..

The Experimental Test Pool measures 15 feet by 30 feet. The pool, which is 15 feet deep, can hold some 50,000 gallons. The ETP is used for shallow-water testing and for workup dives in preparation for OSF dives. Operations are controlled from an instrumented medical and engineering deck that also serves as a platform for monitoring diver status.

The Experimental Diving Facility, which is used for unmanned testing and for evaluation of diving and hyperbaric systems, simulates unmanned pressures up to 1,640 fsw and temperatures between 28 to 110 degrees F.

The DON HRPP's visit to NEDU, team members said, was a stimulating and refreshing look at how the Navy operates when missions and lives are at stake.

A NEDU Master Diver, discussing the command's challenging mission, said that "NEDU's divers take risks to test equipment and procedures for which no standards exist—so divers out in the fleet won't be forced to take those same risks."

DOD HRPP Day: On Nov. 14 the Defense Department will sponsor a full day of sessions on defense-related human research issues, in conjunction with the HRPP Conference sponsored by PRIM&R (Public Responsibility in Medicine and Research) and ARENA (Applied Research Ethics National Association) Nov. 15-18 in Washington, D.C., at the Marriott Wardman Park Hotel. Check the PRIM&R web site(http://www.primr.org/education/conf_future.html) for details.

HRPP Questions and Answers

Education, Classified Research, Scientific Review

Is there a Navy HRPP website that spells out the education policy and the training requirements for Institutional Signatory Officials? Is the CITI website available for training?

The Navy's Human Research Protection Program website currently is under construction. When it is available, we'll send an email to everyone listed in the DON HRPP directory. The website will provide comprehensive information on the Navy's HRPP.

The website also will provide a new HRPP education policy, which will describe training requirements for all personnel who conduct, review, manage, or oversee research—Commanding Officers, directors, investigators, IRB chairs and members, IRB staffers, etc. The policy is close to being finalized.

In late February the DON HRPP staff evaluated the CITI training modules. DON personnel will go through training using modules tailored to their roles and responsibilities in human research. Because the education policy is linked to CITI with its DON-specific module, the training will be available when the policy and the modules are complete and have been approved for dissemination.

Until the DON education policy and CITI are implemented, investigators may complete either their command's own training program or the National Institutes of Health (NIH) training at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

Prior to completion of the DON policy and CITI, Commanding Officers (Institutional Signatory Officials), IRB Chairs, and Human Research Protection POCs who are required to go through training in order to meet assurance requirements, must complete Assurance training modules at the website http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp.

Does the Defense Department or the Navy have any information on IRB review of classified experiments? Is there an official policy?

The Advisory Committee on Human Radiation Experiments (ACHRE) developed recommendations for a policy in a report published in October 1995. The report is available on the ACHRE website at www.eh.doe.gov/ohre/roadmap/achre/index.html.

In a memorandum of March 27, 1997, the White House implemented the ACHRE recommendations, with some modifications. The policy can be viewed at www.eh.doe.gov/ohre/roadmap/whitehouse/appe.html

The Federal Register revised the categories of minimal risk that can be reviewed under expedited procedures. It stipulated that the expedited review procedure may not be used for classified research involving human subjects. The Secretary of Defense's December 13, 1999 memorandum requires SECDEF approval of all classified research with human subjects and spells out the submission process. The forthcoming DON HRPP handbook will provide necessary guidance.

What is the current guidance regarding scientific review of exempt research? Since exempt research is not always reviewed by an IRB, is it possible that exempt research need not undergo scientific review?

The forthcoming revision of the Navy's instruction on human research protection, SECNAVINST 3900.39D, requires an independent scientific review for all human subject research prior to review by the IRB. Even though research may meet the criteria for exemption, it is not subject to a less-stringent standard for scientific merit.

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